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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/537,052 | 06/02/2005 | Allan Shepard | 2335 US F | 8397 |
| Teresa J Schultz Alcon Research R & D Counsel Q 148 6201 South Freeway Fort Worth, TX 76134-2099 | | | EXAMINER HUANG, GIGI GEORGIANA | |
| | | | ART UNIT 1612 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,052

Applicant(s)

SHEPARD ET AL.

Examiner

GIGI HUANG

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
4a) Of the above claim(s) 3-8 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1 and 2 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 02 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 10/13/2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I and the election of species SB 331750 in the reply filed on September 15, 2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Upon examination, the cathepsin K antagonist is expanded to include tunicamycin.

Status of Application

2. Applicant has elected Group I in response to restriction requirement and elected the cathepsin K antagonist species SB 331750 for the examination which has been expanded to include tunicamycin.

Due to restriction, based on election of Group I and the species election, claims 3-8 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Claims 1-2 are present for examination at this time.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The instant claim 1 is directed to a compound defined by reference to desirable characteristics or properties, namely, that the active ingredient is a "cathepsin K antagonist".

The claim covers all compounds having these characteristics or properties, whereas the application provides support for only some compounds within the scope of what is claimed. However, there is no evidence that there is any per se structure/function relationship between the disclosed compounds and any others that might be found using the claimed method. Structural identifying characteristics for the group of cathepsin K antagonist compounds are not disclosed. Therefore, the claimed invention is not supported by adequate written description.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation or any combination thereof. In the instant, the only factor present in the claims is a recitation of broad classes of active agents, which encompass compounds with varying structure, activities and pharmacological profiles. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genera, aside from the specific compounds recited in the specification. The recited genera of active

agents are so broad that the claims effectively read on any and all biological chemical compounds.

Additionally, the term "cathepsin K antagonist " is not adequately described as it is defined by a functional characteristic where it is defined by what it *does* and not what it *is*. Second, it does not describe adequately the degree of access, binding, or activity to the receptor to ascertain what compounds would fulfill the description. As a result, the fact pattern indicates that the artisan was not in possession of the claimed method of use.

It is also noted that at the time of the invention and since, there are still screening methods used to ascertain compounds that potentially have cathepsin K antagonistic activity as evidenced by Mancini et al. (U.S. Pat. 6346373- Col. 10 line 5-13) and Loughran, JR. et al. (U.S. Pat. Pub. 20070020666-paragraph 51). As a result, not all compounds that are cathepsin K antagonist are known and Applicant would not be in possession of the myriad of compounds embraced by the claims.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" as addressed for 1,3-bis(acylamino)-2-propanone derivatives, pyridoxal propionate derivatives, α -alkoxyketone derivatives, cyanamide

derivatives is indefinite as it unclear is encompassed by the term and given the form any number of compounds given an infinite number of chemical reactions, the compounds and be anything and thereby it is unclear what is envisioned for the invention. It does not allow one of skill in the art to know the metes and bounds of the invention.

8. Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 contains names including AC-3-1, AC-3-3, SB-357114 for example, whereby the names are lab designations which are analogous to tradenames and when used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A propriety lab name designation, trademark, or trade name is used to identify a source of goods, and not the goods themselves. Thus, a lab name designation, trademark, or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe several of the compounds in the claim rather than a chemical name (e.g. IUPAC) or a chemical structure, or a known drug name (e.g. tunicamycin) and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claims 1-2 are rejected under 35 U.S.C. 102(a) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 1-2 are rejected under 35 U.S.C. 102(e) as being anticipated by Banerjee et al. (U.S. Pat. Pub. 2002/0160979).

Banerjee et al. teaches a method for inhibiting angiogenesis comprising administering a composition comprising a nucleoside, particularly tunicamycin. The

conditions include neovascular glaucoma (Abstract, paragraph 29, 38, 41, 85, 99, 103-104, 110, 193-199, 207, 212, Claim 1, 5, 9, 15, and 18).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

Conclusion

13. Claims 1-2 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Zohreh A Fay/
Primary Examiner, Art Unit 1612